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ATTN: SARAH KIRKPATRICK, I.P. RIGHTS
ALSIUS CORPORATION
15770 LAGUNA CANYON ROAD, SUITE 150
IRVINE, CA 92618

EXAMINER	
THISSELL, JEREMY	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 9

Application Number: 10/057,334
Filing Date: January 23, 2002
Appellant(s): ALIBERTO ET AL.

John L. Rogitz
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 14 January 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences that will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 5 and 8 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,486,208	Ginsburg	1-1996
5,486,204	Clifton	1-1996
3,425,419	Dato	2-1969
5,716,370	Williamson, IV et al	2-1998

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg 5,486,208 in view of Clifton (US 5,486,204).

Ginsburg teaches all the claimed subject matter including use of the cooling catheter during surgery (col. 2, line 51) except for specifically teaching that the surgery is on an aneurysm. Clifton teaches that it is well known to induce systemic hypothermia to treat patients undergoing aneurysm surgery (col. 1, line 36). It would have been obvious in view of Ginsburg's broad teaching that the device can be used during surgery, to use it during aneurysm surgery as taught by Clifton in order to lower the body's requirement for oxygen. Induced hypothermia has long been used during surgery, as demonstrated by Clifton who uses cooling blankets (col. 4, lines 40-41). Ginsburg teaches that his method of using a catheter is superior to older simpler methods of heat transfer such as cooling blankets (col. 1, lines 63-64) or immersion (col. 2, lines 39-41). It would have been obvious to one of ordinary skill in the art to use a superior cooling technique as taught by Ginsburg to cool the body during surgery which is well-known as taught by Clifton.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dato (US 3,425,419) in view of Williamson, IV et al (Us 5,716,370).

Dato teaches use of a heat-exchange cooling catheter to cool a patient during heart valve surgery (col. 1, lines 32-35). However, the surgery is "open-heart surgery,"

which involves a thoracotomy (or opening the chest cavity to expose the heart). However, Dato's patent dates back to 1965. In the last 37 years, the art of heart surgery has progressed to such a degree that many procedures are now performed in a minimally invasive manner (without the thoracotomy). Williamson teaches that it is well-known to perform valve surgery, in a minimally invasive manner, while inducing hypothermia (col. 2, line 6; col. 8, line 28). In view of the progression of heart surgery, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the heat exchange device of Dato to provide hypothermia during a minimally invasive heart surgery as taught by Williamson in order to efficiently provide a global state of hypothermia without the drawbacks of other cooling methods as discussed by Dato (col. 1, lines 36+).

(11) Response to Argument

With regard to claim 5, Appellant argued that Ginsburg does not explicitly mention that the cooling for the general purpose of surgery is to be undertaken using a catheter, and cites column 2, line 51. However, this passage, when read together with the two ensuing paragraphs makes it clear that induced hypothermia is used during surgeries, and that there exists a need for internal cooling, and that Ginsburg teaches a cooling catheter to meet that need. An appropriate reading of Ginsburg would be that it teaches a heat exchange catheter for, among other things, cooling the patient either from a hyperthermic state or into a hypothermic state in certain situations including surgery.

Appellant also argued that the catheter of Ginsburg is not taught to be capable of inducing severe forms of hypothermia such as "profound hypothermia" taught by Clifton. Brief, page 4. Appellant more specifically argued that although Ginsburg is taught to be capable of establishing a balloon surface temperature of zero degrees Celsius, Ginsburg does not tie this capability to inducing "profound" hypothermia as in Clifton. The argument is that if Ginsburg could not induce profound hypothermia, then it would not have been obvious to use Ginsburg during aneurysm surgery as in Clifton, because it would not be able to sufficiently reduce the body's temperature as necessary.

Induced hypothermia is widely used throughout the medical industry to reduce the body's requirement for oxygen. Ischemia is the general term used to describe a deficiency in the blood supply to a particular organ. Global ischemia is overall low blood supply to the body as a whole. Ischemia can result from different events, such as 1. the sedation of surgery, 2. vascular surgeries where blood flow may be obstructed by tools or vessels purposely occluded for the procedure, and 3. artificial cardiopulmonary bypass where the patient's blood is circulated outside the body and literally pumped through the body using external equipment while the heart is kept from beating (the external pump is not as efficient as the hearts natural pumping action). By inducing hypothermia, surgeons can prevent ischemic injury of tissues (i.e. damage due to oxygen deficiency).

During any vascular surgery, such as aneurysm surgery, where tools will be introduced into blood vessels, there is the possibility of restricting blood flow, and therefore the desirability (one of ordinary skill in the art might even say "need") to cool

the patient systemically to prevent ischemia. Clifton does, in fact, teach the use of induced hypothermia during aneurysm surgery. Clifton, col. 1, lines 33-36.

With regard to the capability of Ginsburg to provide a level of cooling sufficient for use in aneurysm surgery, the Examiner refers to Ginsburg col. 6, lines 56-65, which teach that catheter surface temperatures of between 37-42 degrees Celsius (Note that 37 degrees is body temperature) will raise the core body temperature roughly 1-2 degrees Celsius per hour. To give an idea of the cooling capabilities of Ginsburg, it seems that if a difference of 0-5 degrees from body temperature will alter the core body temperature about 1-2 degrees per hour, a difference of 37 degrees (zero degrees catheter surface temperature as in Ginsburg) will lower body temperature at a significant rate. Granted, cooling is somewhat more difficult because of the body's natural defense mechanisms that try to heat itself back up, but comparing a temperature gradient of 5 degrees to one of 37 degrees, it seems that the catheter is more than capable of reducing body temperature to a sufficient level to prevent the ill effects of ischemia. In fact, a comparable cooling procedure was done in Dato (US 3,425,419) Dato is later discussed with regard to the other rejection rendered in this case. However, we can coincidentally look to it for an example. Dato discusses the effect of a large temperature gradient and that a cooling catheter circulating a fluid at zero degrees Celsius will reduce the body temperature roughly 8 degrees Celsius in only 30 minutes. Dato col. 4, lines 1-15. At that rate, it would take less than an hour to cool the body to profound hypothermic levels (~24 deg C.) This is a rough estimate as there are other factors to consider, such as the fact that the colder the body gets, the lower the

temperature gradient is. However, it shows that the device of Ginsburg is more than capable of inducing profound hypothermia in a reasonable time frame.

With regard to the discussion of cooling blankets. The Examiner agrees that Ginsburg does not teach "cooling" blankets. However, it broadly discusses older, simpler heat exchange methods, including external methods such as blankets (col. 1, line 3) and immersion (col. 2, line 39-40). Ginsburg is referring to the external application of heat or cold to the body. One of ordinary skill in the art would recognize that the cooling blankets of Clifton, applying cold to the external surface of the body, is a use of "older and simpler" techniques discussed as inadequate in Ginsburg.

With regard to claim 8, Applicant argued first that the device of Dato is used for thoracotomy (opening the chest cavity to expose the heart), and that therefore it cannot be assumed that it could be used for minimally invasive surgery. However, Dato's figure 3 clearly shows that the device is administered through the femoral vein. (See also col. 2, lines 47-50). Since the device is not introduced through the opening in the chest wall, the device is sized and configured for conventional minimally invasive insertion, such as the femoral route used by Dato himself.

Applicant argued second that Williamson does not teach induced hypothermia, but alleges that the passage in Williamson at col. 2, lines 4-7 is referring to accidental hypothermia that can occur in the operating room. This is incorrect. Williamson provides a heart valve that pops open and thereby seats itself in position as opposed to requiring the surgeon to suture it in place. Williamson mentions in col. 2, lines 4-7 that

the suturing takes too long and that this extra time required "lengthen[s] the time the patient is ***on*** cardiopulmonary bypass and hypothermia." Williamson does not say that this extra time increases the risk of hypothermia. He says that it lengthens the time that the patient is on hypothermia, hypothermia being a treatment regimen much like being on antibiotics. While hypothermia reduces the risk of ischemia, it can have its own ill effects particularly if sustained too long. Williamson recognizes that while induced hypothermia is a necessary component of this surgery, he also recognizes that, like other aspects of surgery (e.g. anesthesia, bleeding, etc) it should be minimized.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

J. Thissell
August 10, 2003

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Conferees
B. Casler

A. Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

ALSIUS CORPORATION
15770 LAGUNA CANYON ROAD, SUITE 150
IRVINE, CA 92618